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223 NAME OF RESPONSIBLE INDIVIDUAL Charles L. Houston, III, Captain USAF

83 APR edition may be used until exhausted. All other entions are obsolete

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202-693-1556

Date: June 8, 1988

ANNUAL REPORT ON CONTRACT NOO014-87-F-0107

PRINCIPAL INVESTIGATOR: R. W. Waynant

CONTRACTOR: Food and Drug Administration

Center for Devices and Radiological Health

Electro-Optics Branch

CONTRACT TITLE: Evaluation of Single Crystal Sapphire Fibers for Medical Purposes

START DATE: 1 June 1987

RESEARCH OBJECTIVE: To evaluate for medical applications the sapphire fibers produced under a coordinated contract (University of South Florida, Dr. N. Djeu). To determine transmission, optical breakdown resistance, and bending strength of sapphire fibers.

PROGRESS (Year 1): We have assembled a fiber processing and testing facility capable of cutting, stripping and polishing sapphire and other fibers. This equipment enables us to polish the fibers for further research or to fabricate them into the connectors commonly used in medical equipment. In addition, we have assembled a testing and measurement facility to measure transmission of the fibers over a broad bandwidth and to determine the breakdown strength of these fibers at laser wavelengths of interest in the medical community. All of the information obtained uder this contract is fed back into the growth program at the University of South Florida for further development of improved medical device fibers.

initially work was devoted to the selection and procurement of a fiber polisher, a microscope capable of inspection of the polished ends and a fiber microinterferometer to measure the flatness of the polished ends. These pieces of equipment have been tested with silica and infrared fiber materials as well as with the sapphire fibers supplied by the University of South Florida. The technology of polishing sapphire, while well known in the material sciences, is not obvious and some time was devoted to developing the needed in-house capability. Figure 1 shows the importance of high quality polishing of sapphire and its effect on transmission. The lower curve shows the transmission of the sapphire boule made using hand polishing and having optically acceptable surfaces. The second curve shows the effect of continued polishing with finer grit of diamond material.

Data from "Sapphire Boule "

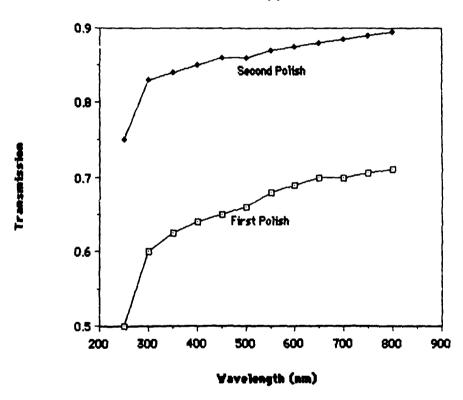


Figure 1

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Considerable effort has gone into acquiring the skills and techniques of mounting the fibers into connectors. Techniques have been developed for the alteration of the commonly used communications connectors to accept an assortment of sizes of medical fibers.

We have received three fibers from the University of South Florida; two have been polished and are being evaluated; the third is being polished and assembled. Transmission measurements have been made for one fiber grown in the c-axis direction. These measurements show high losses in the ultraviolet, but good transmission beyond about 600 nm. Since the short wavelength transmission of these fibers depends highly on the quality of the starting material, we are investigating the transmission of the starting material. The growth equipment at the University of South Florida has the capability to grow fibers under inert atmospheres which may eliminate impurities such as water vapor that can drastically affect the fiber transmission.

RELATED WORK AT FDA:

Evaluation of ball-tipped fibers for angioplasty: FDA has interest in many aspects of fiber optic laser delivery. Once such interest is in evaluating the performance of fibers for angioplasty. Our interests here include the coupling efficiency from laser to fiber; the ability of the fiber to deliver the required laser energy without breakdown or burn-back; and the ability of the fiber end to deliver the energy to the location required without undue damage to the fiber and without undue damage to arterial tissue due to excessive heating, sticking or other problem. Our work here is being done in collaboration with Walter Reed Army Medical Center using the minature Yucatan swine as the animal model.

Evaluation of the temperature and emission patterns from surgical and endoscopic fibers: FDA's interest in the fiber tips extends beyond angioplasty. Fibers are used routinely for delivery of surgical energies both endoscopically and in hand held scalpels for surgery. The emission patterns and tip temperatures are important in assessing the likely thermal damage the instrument will produce and in assessing the potential damage the scattered radiation may induce. Our work here has shown that the focusing effects of a ball tip induces bubble formation in blood saline solutions and that these bubbles can be driven by laser radiation. Further investigations of these effects are underway.

Fabrication of fiber surgical devices: The broad perspective that FDA has in the medical arena sometimes leads to ideas for the improvement of devices. In the fiber area several ideas for both improved surgical tips and other surgical devices are being investigated. Improvements to fiber tips that lower the temperature, prevent sticking due to excess heat, and prevent damage by keeping the emitting surface cleaner, are being made. Illuminators for ocular surgery have been made which spread the light over a much greater surface area than a single fiber. Plans include the fabrication of special shapes of surgical devices to allow scar tissue to be removed from retinas.

Investigations of breakdown in optical fibers and components: FDA is greatly interested in the NBS Free Electron Laser as a versatile research and surgical tool. This device will operate in a picosecond pulsed, multi-Megahertz repetition rate with average power in the tens of watts. Not only does this operation make breakdown of fibers from the high peak power a concern, but the average power will be a problem as well. Successful operation of such a device will require broadband fibers capable of withstanding both high peak and average power. FDA is looking at all commercial fibers in an effort to find the best materials as well as to investigate such problems as sterilization and toxicity.

Mutagenic studies of excimer laser wavelengths: FDA has been concerned for many years about the hazards of ultraviolet wavelengths. It is similarly concerned about the risks of doing surgery with very intense laser beams in the ultraviolet, but realizes that benefits may overcome the risks. In carrying out research to help quantify the risks, comparisons have been made between the effects of 248 nm radiation and 193 nm radiation on an in vitro assay system. These studies have confirmed that the extremely short wavelength 193 nm radiation is less mutagenic than 248 nm radiation. Measurements of other excimer wavelengths will be carried out shortly. Concern for the medical proceedure and the type of tissue being irradiated may dictate excimer use. Mutagenic effects due to multiphoton triggered reactions dictate concern for FEL operation even in the visible. In addition, work at FDA has shown that the fluorescence of agar plates (and possibly tissue fluorescence) falls in the mutagenic spectral region.

investigations of viral transmission in laser plumes: The expanding presence of AIDS virus causes FDA concern for the safety of laser surgery and its accompanying vaporization of material. Are infectious viruses able to be transmitted from laser irradiated tissue to others who might contact the debris? Experiments in our laboratory have shown the transmission of Phi-x virus from one agar plate to another a few centimeters away.

Extension of these studies to more realistic conditions will be carried shortly.

FUTURE PLANS (Year 2): During the next year we plan to continue to measure the transmission of the sapphire fibers as well as to monitor the optical transmission of the bulk sapphire material from which fibers are pulled. This will enable a continuous monitoring of our progress as we improve the transmission of the fiber. In addition, the long wavelength measurements will be extended to at least ten microns using the monochromator just purchased. Sapphire material normally transmits to wavelengths as long as five microns and low loss sapphire could be useful in the infrared for transmitting Er:YAG laser emission. New materials such as CaF2 could be a durable fiber for tunable FEL emission in the future and its growth should be initiated. In addition to transmission studies, we will also make measurements of fiber breakdown strength at important wavelengths and will attempt to correlate the results with growth techniques and bulk material properties. Finally, since the bending strength of the fiber is important to angioplasty and other catheter applications, the minimum bending radius of sapphire fibers will be determined as a function of fiber diameter and crustal axis.

PUBLICATIONS AND REPORTS (Year 1): While publications devoted only to this research have not yet been prepared, this research has been mentioned in the following publications and presentations.

- 1) R. W. Waynant, "Ultraviolet Lasers in Medicine: A Review of Progress" in Excimer Lasers and Their Applications", R. Sauerbrey, ed. SPIE Transaction (to be published), Los Angeles, CA, Jan 10-15, 1988.
- 2) R. W. Waynant, "Short Wavelength Lasers: Status and Applications in Science and Medicine", presentation at Andrews University, October 15, 1988.
- 3) D. Royston, R. Waynant, A. Banks, S. Ramee, and C.J. White, "Optical Properties of Fiber Optical Surgical Tips", presented at Optical Society of America meeting, Rochester, NY, October 18, 1987.
- 4) D. Royston, R. Waynant, A. Banks, S. Ramee and C. J. White, "Optical Properties of Fiber Optical Surgical Tips in Liquids and Blood," presented at International Laser Science Conference, Atlantic City, NJ, November 2, 1987.

- 5) R. W. Waynant, "Ultraviolet Lasers in Medicine: A Review of Progress," presented at SPIE Los Angeles meeting January 10-15, 1988.
- 6) R. W. Waynant, "The Uses of Lasers in Medicine and Surgery," presented at Delta Sigma Pi (business fraternity) meeting, Johns Hopkins University, Baltimore, MD, March 11, 1988.
- 7) R. W. Waynant, "The Uses of Lasers in Medicine and Surgery," presented at Department of Electrical Engineering Seminar, University of Maryland, March 25, 1988.

FINANCIAL REPORT YEAR 1

Actual Purchases		Amount
First Year Major Purchases		
Microinterferometer		\$6920.00
Optical Components		9596.00
Monochromator		10165.00
Digital Delay Generator		3645.00
Digitizer		22262.00
Glass Lathe		5355.00
Travel		2409.00
Supplies		
Microball lens		499.00
Fibars		512.00
Lenses		935.00
Video Data Recording Accessories		470.00
Fibers		485.00
Power Supply		995.00
Optical Table		4443.00
Abrasives		249.00
Precision Drill		3191.00
Consultant-Fiber Fabrication		\$ 4000.00
	Total	\$77210.00

^{**} The time domain reflectometer required for short fiber lengths was more expensive than budgeted. At the same time a monochromator is needed for transmission measurements and has been purchased. The time domain reflectometer is being purchased with second year funds and is reported here under committed funds.

Due to the effects of timing and budget requirements, the polisher scheduled for SDIO purchase for this contract was purchased by FDA funds. The high speed camera scheduled for purchase with second year funds cannot be purchased due to funding limitations. A digitizer for fast signal acquisition was purchased as listed above.

It should be pointed out that the time domain reflectometer being purchased is anticipated to be compatible with the FEL and, when used with the NBS FEL, will make a unique device for measurements of pulse propagation in fibers. Information obtainable with this device should be useful in both communications sciences and in medical fiber studies.

FUNDS COMMITTED/OBLIGATED

Time Domain Reflectometer	45,000.00
Consultant-Polishing Expert	5,000,00
TOTAL	50,000.00

Both of the above items have been ordered, but have not been received.

ANTICIPATED EXPENDITURES

These expenditures use up the available funds for 1988-89 fiscal year. When third year contract funds become available, the third year expenditures anticipated are:

Ultrafast Camera		61,000.00
Travel		2,000.00
Supplies		8,000.00
Consultant	Total	<u>4,000.00</u> 75,000.00

PROPOSED ADDITION TO CONTRACT

As discussed briefly on a previous occasion, we believe laser damage to fibers will be a serious difficulty for the MFEL program. In the present program we will be doing everything possible from an experimental viewpoint to prevent laser damage and optical breakdown. We believe it would be useful to have assistance in the theory of breakdown from a superb

numerical physicist, Dr. Curtis Menyuk of the Department of Electrical Engineering of the University of Maryland. Dr. Menyuk would perform several types of calculations that could be instructive both now and in the transition to the FEL at Gaithersburg. One calculation would be to determine the increase in electric field due to the presence of defects in fibers and to evaluate experimental changes that could be made in the growth process to lessen the susceptibility for damage that defects might have. A second calculation to determine the optimum pulse shape for the reduction of dielectric stress, within the capabilities of the conventional or free electron laser, would help prevent fiber damage.

It is estimated that a reasonable effort on this problem could be achieved for about \$25,000.00. If this amount were added to our contract, we could set up a contract with Dr. Menyuk and handle its administration.